



REQUEST FOR PROPOSALS

Performance Audit Services
CIRM RFP #2272

June 13, 2011

The California Institute for Regenerative Medicine invites interested bidders to review and respond to this Request for Proposals (RFP), entitled RFP #2272 Fiscal Year 2010-11 Performance Audit Services for the California Institute for Regenerative Medicine (CIRM). The RFP seeks Performance Auditing services for the first triennial performance audit of CIRM's functions, operations, management systems, and policies and procedures for fiscal year 2010-11.

Prospective bidders interested in responding to this RFP are encouraged to email the contact person listed below by July 6, 2011, indicating their interest with the firm's name, address, and email address where future notifications can be sent. Submitting the email will ensure that your firm receives supplemental or updated information that might be released subsequent to CIRM's formal issuance of the RFP.

Proposals are due by 5:00p.m. on August 5, 2011.

In the opinion of CIRM, this RFP is complete and without need of explanation. However, if prospective bidders have questions, notice any discrepancies or inconsistencies, or need any clarifying information, questions may be submitted to CIRM no later than the date stated in Section C.1, Key Action Dates. Please note that no verbal information given will be binding upon CIRM unless such information is issued in writing as an official addendum or as answers to bidders' written questions.

The contact person for this RFP is:

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A. Purpose and Background

1. Purpose

The California Institute for Regenerative Medicine (CIRM) is requesting proposals from qualified independent public accounting and consulting firms for performance audit services. Health & Safety Code section 125290.30, subdivision (c) mandates that CIRM commission a performance audit every three years beginning with the audit for the 2010-11 fiscal year. The performance audit will examine the functions, operations, management systems, and policies and procedures of CIRM to assess whether it is achieving economy, efficiency, and effectiveness in the employment of available resources. In addition, the audit will examine whether CIRM is complying with policies and procedures established by its governing board.

The focus of the performance audit is on CIRM's process for grants award and administration, rather than the scientific goals and performance of the research funded by the grants. The statute specifically excludes scientific performance from the scope of the audit. The statute mandates that this first triennial performance audit will include, but not be limited to, all of the following:

- Policies and procedures for the issuance of contracts and a review of a representative sample of contracts;
- Policies and procedures for the issuance of grants and loans and a review of a representative sample of grants and loans; and
- Policies and procedures relating to the protection or treatment of intellectual property rights associated with research funded or commissioned by CIRM.

2. Background

This section provides a high level summary of CIRM functions and operations and is intended as background for prospective bidders to assist in their development of proposals to provide performance auditing services. **The following information should not be construed to be an exhaustive or comprehensive description of CIRM's processes and activities.**

a. Overview of CIRM

CIRM was established in early 2005 following the passage of Proposition 71, the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which authorized \$3 billion in general obligation bond funding for stem cell research and facilities at California universities and research institutions, was approved by California voters on November 2, 2004, and called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The mission of CIRM is to support and advance stem cell research, regenerative medicine and other vital research opportunities, to do so pursuant to the highest ethical and medical standards, and to discover and develop cures, therapies, diagnostics and research technologies to relieve human suffering from chronic disease and injury. To date, CIRM has approved 434 grants/loans totaling more than \$1.2 billion.

Proposition 71 also created the Independent Citizens Oversight Committee (ICOC), which governs CIRM and has full power, authority, and jurisdiction over CIRM. The ICOC has 29 members who are appointed in accordance with specific parameters set forth in statute. ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry. The ICOC members elect a chairperson and vice chairperson, who serve six-year terms and meet certain criteria also specified in the code.

The ICOC's functions are specified in Health and Safety Code section 125290.40 and include the following duties relevant to this performance audit:

- Develops annual long-term strategic research and financial plans;
- Makes final decisions on research standards and grant awards;
- Ensures completion of an annual financial audit;
- Establishes policies regarding intellectual property rights arising from research funded by CIRM;
- Establishes rules and guidelines for the operation of the ICOC and its working groups; and
- Adopts, amends, and rescinds rules and regulations to carry out Proposition 71 and to govern the procedures of the ICOC.

Three scientific and medical working groups advise the ICOC but do not have final decision-making authority. They provide guidance related to ethical standards, grants review, and facilities as follows:

- The Scientific and Medical Accountability Standards Working Group (Standards Working Group), made up of patient advocate members of the ICOC, ethicists, and clinicians, makes recommendations regarding medical and ethical standards for obtaining research materials and for the conduct of clinical trials.
- The Scientific and Medical Research Facilities Working Group (Facilities Working Group), made up of patient advocates from the ICOC and real estate specialists, makes recommendations regarding funding for buildings and capital equipment including the setting of milestones and timetables.

- The Scientific and Medical Research Funding Working Group (Grants Working Group), draws from over 100 stem cell science experts from outside California and from patient advocates on the ICOC, reviews applications for funding and makes recommendations as to which applications should be funded.

The President serves as CIRM's chief executive officer and oversees 47 professional and support staff. The President's primary responsibilities are to recruit the highest scientific and medical talent in the United States to serve on working groups; to serve CIRM on its working groups; to direct ICOC staff and participate in the process of supporting all working group requirements to develop recommendations on grants, loans, facilities, and standards as well as to direct and support the ICOC process of evaluating and acting on those recommendations; the implementation of all decisions on these and general matters of the ICOC; to hire, direct, and manage the staff; to develop the budgets and cost control programs; to manage compliance with all rules and regulations of the ICOC, including the performance of all grant recipients; and to manage and execute all intellectual property agreements and any other contracts pertaining to CIRM or research it funds.

CIRM has policies in place for its internal administrative procedures, regulations for its grant making activities, and procedures to be followed by grantees. All of the policies, procedures, and regulations will be provided to the successful bidder after the award of the contract.

b. Contracts

Although CIRM is a State agency, Proposition 71 allowed it to adopt procurement policies based on University of California policies, which differ from other California State agencies. CIRM's adopted contracting policies, which are based upon University of California Business and Finance Bulletin 34, can be found on CIRM's website (see Appendix 2).

Approximately 90 contracts will have been issued during the 2010-2011 fiscal year for services including independent consultants, hotel agreements, and support services, such as legal, accounting, and information technology. In addition, CIRM issues purchase orders for goods and services paid through Cal Card, AMEX, or warrants. CIRM anticipates approximately 500 purchase orders will be issued during this fiscal year, the vast majority of which are less than \$1,000. CIRM utilizes an Excel spreadsheet to track the issued purchase orders.

CIRM contracts its accounting functions to the California Department of General Services (DGS) through an Interagency Agreement. Once CIRM verifies receipt of goods or services, two full-time equivalent staff at DGS are responsible for all of the accounting processes and adhering to the internal controls established by DGS. This includes encumbering contracts and certain purchase orders, processing payments, recording vendor payment history, and closing the books in the California State

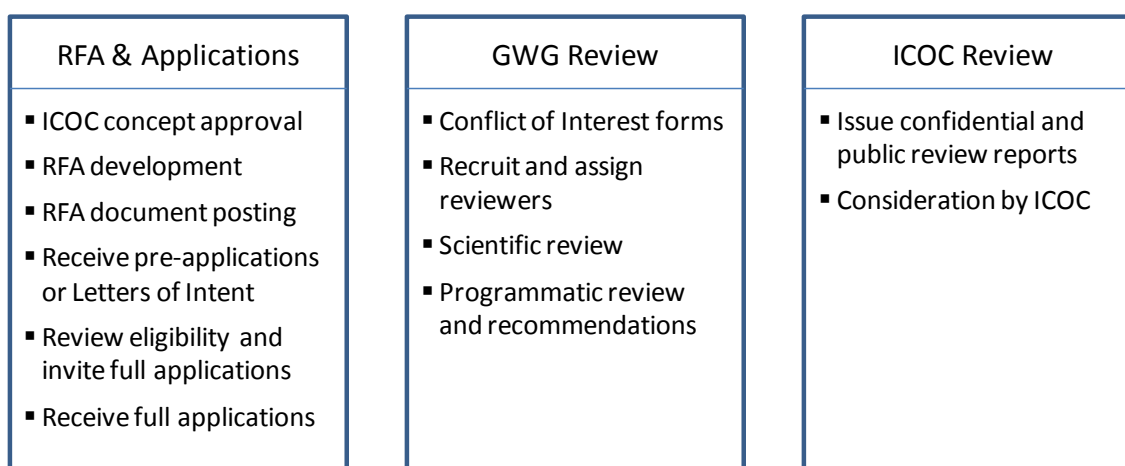
Accounting and Reporting System (CalSTARS). CIRM does not have access to CalSTARS. At year-end, CIRM conducts balance reconciliation with a hard-copy, CalSTARS-generated printout. The annual CIRM financial audit covers most of the accounting function, including formal testing of accounting transactions.

c. Grants Application, Review, and Approval

CIRM's Grants Review Office manages the application, review and approval process. The process is guided by Proposition 71, the Grants Administration Policy, and the Grants Working Group Bylaws. As shown in Figure 1, during the RFA & Applications Phase, CIRM scientific staff develop a concept for a funding program, based on the initiatives in CIRM's Strategic Plan. CIRM staff present the written concept—including a description of the objective, high-level eligibility requirements, and the estimated funding amount for the concept—to the ICOC for approval. If approved, CIRM scientific staff develop the Request for Application (RFA) document. The RFA document is an official solicitation for applications directed to a particular funding opportunity. Each RFA document specifies the objectives and applicable requirements, eligible costs, and the review criteria that will be used to evaluate the merits of applications submitted in response to the RFA document.

The RFA document may require either Pre-Applications or Letters of Intent (LOI). For pre-applications, CIRM scientists and outside experts identify which proposals will be invited to apply. For LOI's, CIRM staff review the letters to determine the Institution and primary investigator's (PI) eligibility and accept applications from all that are qualified to apply.

Figure 1: Application Review and Approval Process



During the GWG Review Phase, designated representatives of the Grants Working Group (GWG) review submitted applications. Each application is reviewed in depth by two or three reviewers who comment on the overall scientific merit of the application

under the specific review criteria defined in the RFA. Review by the GWG follows the procedures described by the GWG Bylaws.

During the ICOC Review Phase, the ICOC may accept, reject, or modify the GWG recommendation for each application. The ICOC authorizes funding of the approved applications.

Table 1 provides information on the approximate number of applications submitted, reviewed and approved in fiscal year 2010-11 by RFA.

Table 1: RFA Activity in FY 2010-2011

Application Process	RFA Activity in FY 2010-2011				
	RFA 1	RFA 2	RFA 3	RFA 4	RFA 5
Pre-Applications/Letters of Intent	112*	226	5	271	71
Invited to Apply	45*	58	4	64	64
Applications Submitted	45*	56	4	63	55
Applications Reviewed	45	56	3	63	35
Applications to ICOC for decision	45	56	1	63	Next FY
Applications Approved	21	20	1	27	Next FY

Note: activities with an asterisk () were conducted in the prior fiscal year*

During both the GWG and ICOC review processes, GWG and ICOC members must ensure they have no conflict-of-interest (COI) issues with any particular application. CIRM staff spend considerable time identifying potential COI issues. CIRM generates a list from a database that captures the names of all individuals, companies, and associated subsidiary companies provided in grant applications. GWG members, ICOC members, and CIRM staff review the list and report in writing any conflicts with the recorded names. The database matches the recorded names to particular applications. Based on reported conflicts, CIRM staff identify recusals for GWG members, ICOC members, and CIRM staff for particular applications. The database also identifies all GWG and ICOC members and their affiliations, which can be cross-referenced to the individuals and companies listed in the grant applications. CIRM staff check the cross-references and notify GWG and ICOC members when there are matches. The GWG or ICOC member must sign a COI statement. In addition, if an application is discussed in a GWG review meeting, any member with a potential COI must leave the room during discussions. During ICOC review, ICOC members must abstain from discussing and voting on any applications for which they have a COI and leave the room during any closed session discussion of those applications.

d. Grants Management

The Grants Management Office is responsible for pre-award review, award acceptance, and monitoring processes, as depicted in Figure 2. During the Pre-Award Review Phase, CIRM staff create a grant file for the approved applications. For each grant, there is an assigned CIRM Grants Management Officer (GMO) and the Scientific Program Officer

(SPO). The GMO and SPO conduct a Pre-Funding Administrative Review (PFAR) prior to funding an approved application. Both the GMO and SPO utilize a pre-funding checklist that details what they must review. During the PFAR, staff verifies eligibility information in the grant application (i.e., confirm that the principal investigator possesses the academic degrees stated in the application) and ensures that approvals are in place as required by CIRM's medical and ethical standards. If the ICOC approves an application subject to conditions or modifications, the GMO and SPO consult with the applicant on how to implement those changes. When the PFAR is completed, both the GMO and SPO sign off on their checklists.

Figure 2: Grants Management Process

Pre-Award Review	Award Acceptance	Monitoring
<ul style="list-style-type: none"> ▪ Administrative and budget review and adjustments ▪ Compliance review ▪ Other conditions 	<ul style="list-style-type: none"> ▪ Notice of Grant Award ▪ Issue pay memo ▪ DGS processes payment ▪ SCO issues warrant 	<ul style="list-style-type: none"> ▪ Scientific progress reports ▪ Annual Financial Reports ▪ Updated assurances and certifications ▪ Compliance visits

During the Award Acceptance Phase, CIRM staff prepare the Notice of Grant Award (NGA), which includes any special terms and/or any budget adjustments noted on the checklists. CIRM's Legal, Financial, and Science offices then review the NGA. Following this review, a CIRM scientific executive signs the NGA and it is mailed to the grantee to sign and return. CIRM staff prepare a pay memo that is signed by the Grants Management and Finance officers, and then sent to the California Department of General Services to process the payment. The State Controller's Office (SCO) then issues a warrant and releases funds to the grantee.

During the Monitoring Phase, the grantee provides various progress reports after the grant has been awarded. The reports contain different information depending on whether the award funded training, research, or facilities. CIRM's grant administration policy (see Appendix 2) and the RFA document list the reporting requirements. The grant management activities for fiscal year 2010-11 are listed in Table 2.

Table 2: Grants Management Estimates for Fiscal Year 2010-11

Grants Management Process	Estimate for FY 2010-11
Pre-Funding Administrative Reviews	85
New Awards	
• Conference grants	7
• Research grants	71
• Research Training or Bridges to Research grants	7
• Facilities grants	0
Grant Award Payments	675
Grantee Progress Reports Submitted	290
Grantee Financial Reports Submitted	250
Grants Closed-Out	115

e. Loans

Some CIRM-sponsored research projects are funded through loans rather than grants. Loans are limited to larger projects (at least \$3 million) undertaken by for-profit applicants. The Loans Administration Policy can be found on CIRM's website (see Appendix 2). Most terms and processes for loans are the same as those for grants. The key difference is that a loan recipient has a conditional obligation to repay CIRM funding, but is not subject to the revenue-sharing provisions of the Intellectual Property regulations. During the audit period, no loan repayments were due or made.

f. Grants Management System

CIRM maintains two systems for managing grants processes:

- 1) A custom developed program for application review and approval. Although software upgrades are currently underway to support the review, post-review, and pre-award review processes, data are available in multiple forms.
- 2) A commercial-off-the-shelf (COTS) solution called MicroEdge Gifts for award acceptance and progress monitoring. Grants Management Office (GMO) staff use the Gifts system to report on activities and individuals across grant programs (different RFAs) and across time.

g. Intellectual Property Policies

Proposition 71 authorized the ICOC to develop intellectual property (IP) policies to obtain a financial return to the State on the bond funding while assuring that essential medical research would not be unreasonably hindered. To develop its IP policies, CIRM conducted 15 public meetings; sought input from the biotechnology, venture capitalist, traditional lending and academic communities; conducted a best practices survey of more than 20 funding entities; held 12 Public Comment Rounds; and responded to

almost 100 formal comment letters submitted under the Administrative Procedures Act. **The adequacy of the IP policies is outside the scope of this performance audit.**

Under the current IP policies (see Appendix 2), CIRM does not own any inventions. However, grantees must notify CIRM about any CIRM-funded inventions and share the resulting revenue. Within 60 calendar days after a CIRM-funded invention has been reported by the principal investigator to the grantee institution's IP/Technology Transfer Office, grantees must submit an Invention Disclosure Form, which identifies the grant, the inventor(s), and the principal investigator. The grantee's disclosure conveys a clear understanding, to the extent known at the time of the disclosure, of the purpose, operation, and physical, chemical, biological or electrical characteristics of the CIRM-funded invention. During the 2010-11 fiscal year, CIRM has received 12 Invention Disclosure Forms.

The grantees must undertake reasonable efforts to bring their inventions to practical use and to share revenue with the State of California based on formulas specified in the IP policies. In addition, if the grantee develops drugs or therapeutic treatments resulting in whole or in part from CIRM-funded research, the grantee must ensure access to eligible Californians and price protections for sales to State agencies and the California Discount Prescription Drug Program. During the 2010-11 fiscal year, no grantee reported a financial transaction that would trigger the IP policy revenue sharing requirement nor did any grantees report commercialization that would trigger the IP policy access or price protection requirements.

Grantees may publish their CIRM-funded finding in scientific journals, or publish an abstract in connection with a scientific meeting, information about a CIRM-funded invention, or a CIRM-funded technology. In the event of a publication, the grantee must submit a Publication Disclosure Form to CIRM. As of April 2011, CIRM has received approximately 104 Publication Disclosure Forms since the beginning of the fiscal year.

Grantees also must submit an Invention Utilization Report to CIRM, which include any patents, execution of license agreements, material transfer agreements or collaborative agreements, annually and for 15 years after the project period of the grant. The elements of the Invention Utilization Report are defined in the IP policies. In fiscal year 2010-2011, CIRM received 18 Invention Utilization Reports, which reported the status of 70 invention utilization activities, such as licensing, patenting, transferring, and sharing. Grantees are allowed to negotiate licenses for commercial development and availability of an invention. In fiscal year 2010-11, three licensing activities were reported in the Invention Utilization reports submitted to CIRM.

Table 3: Intellectual Property Transactions for Fiscal Year 2010-11

IP Transaction Type	FY 2010-11
Invention Disclosure Forms	12
Invention Utilization Reports	18
Publication Disclosure Forms	104 (as of 4/2011)

h. Prior Performance Audits and Studies

Early in CIRM's formation, the Bureau of State Audits (BSA) conducted a performance audit of CIRM and published its findings in February 2007. The audit primarily focused on development of processes for grantee compliance, grantee reporting, and completion of IP regulations. At that time, CIRM had not issued many grants and was still in the process of developing its grant administration, contracting, and IP policies and procedures. The audit identified several areas of improvement to comply with the requirements of Proposition 71 and strengthen internal controls. The BSA conducted several annual follow-up reviews to assess CIRM's progress toward implementing the BSA's recommendations. By the third annual review, CIRM had implemented all of the BSA's recommendations from the 2007 report. The initial report and annual implementation reviews can be found at the following links:

- BSA 2007 Report: <http://bsa.ca.gov/pdfs/reports/2006-108.pdf>
- BSA 2008 update, page 193: <http://bsa.ca.gov/pdfs/reports/2008-406.pdf>
- BSA 2009 update, page 27: <http://bsa.ca.gov/pdfs/reports/2008-041.pdf>
- BSA 2010 update, page 27: <http://bsa.ca.gov/pdfs/reports/2009-041.pdf>

The State Controller's Office also completed a review of CIRM for the period of July 1, 2006, through December 31, 2007. The objectives were to determine whether CIRM complied with the requirements of Proposition 71, as it related to conflict-of-interest policies, grant administration, administration expenses, and expenditures. Except for an issue concerning specialists' failure to sign post-review conflict-of-interest certification forms, the SCO found that CIRM's conflict-of-interest policies were adequate, and that they were properly followed. In addition, the SCO tested a sample of grants to determine whether the grants were administered in compliance with Proposition 71 and the policies and procedures established by the ICOC. The SCO found that CIRM was in compliance with the allocation and administration of its grants. This report can be found at: <http://www.sco.ca.gov/Press-Releases/2008/pr08026review.pdf>.

In June 2009, the Little Hoover Commission published its review of CIRM. Senators Kuehl and Runner asked the Commission to recommend ways to strengthen the governance structure, improve accountability and reduce conflict of interest. This report can be found at: <http://www.lhc.ca.gov/studies/198/report198.html>. Subsequently, Senator Alquist introduced SB 1064 to address some of the issues raised by the Commission's report related to oversight and transparency. Senator Alquist's

bill, which amended the California Stem Cell Research and Cures Act, was signed into law (Chapter 637) on September 30, 2010. It included the mandate for triennial performance audits.

In 2010, CIRM commissioned an external review to formally assess CIRM's 2006 Scientific Strategic Plan. An External Advisory Panel (EAP), comprised of an international group of experts in stem cell research, ethics, and biotechnology, conducted comprehensive interviews and inquiries with the ICOC, CIRM staff, Grants Working Group members, patient advocacy group representatives, scientists, trainees and industry leaders in the stem cell community. During the course of the review, the EAP evaluated CIRM's programs against its goals; assessed effectiveness in moving CIRM towards meeting its goals and accomplishing its mission; recommended changes in CIRM's funding priorities to ensure that CIRM is supporting the most promising advances in the field of regenerative medicine; and provided other feedback as necessary. The EAP issued a report with its conclusions and recommendations that focus on the scientific aspects of CIRM's mission. This report can be found at: http://www.cirm.ca.gov/files/PDFs/Administrative/CIRM-EAP_Report.pdf.

CIRM does not expect the performance auditor to assess CIRM's progress toward implementing the EAP's recommendations since the statute excludes a review of scientific performance in this performance audit.

Finally, as required by Proposition 71, CIRM commissions an annual independent financial audit of its activities from a certified public accounting firm. The findings are provided to the SCO each year, which then reviews the audit and issues a public report of that review. Proposition 71 established the Citizen's Financial Accountability Oversight Committee (CFAOC), which is chaired by the State Controller. This committee reviews the annual financial audit, the SCO's report and evaluation of that audit, and the financial practices of CIRM. Neither the SCO nor the CFAOC has a role or responsibility in reviewing the triennial performance audit requested through this RFP. Prior CFAOC reports can be found at: http://www.sco.ca.gov/eo_about_cfaoc_rpts.html.

B. Statement of Work

1. Services to be Provided

The selected bidder will conduct a performance audit of CIRM's functions, operations, management systems, and policies and procedures for the 2010-11 fiscal year. The performance audit objectives and audit scope are defined in Health & Safety Code section 125290.30, subdivision (c). The performance audit will assess: 1) whether CIRM is achieving economy, efficiency, and effectiveness in the employment of available resources; and 2) whether CIRM is complying with ICOC policies and procedures.

The statute indicates that the audit scope must include, but is not limited to, a review of: 1) policies and procedures for the issuance of contracts and a review of a representative

sample of contracts; 2) policies and procedures for the issuance of grants and loans and a review of a representative sample of grants and loans; and 3) policies and procedures relating to the protection or treatment of intellectual property rights associated with research funded or commissioned by CIRM. **The statute excludes a review of scientific performance from the scope of this audit.**

The performance audit must be conducted in accordance with generally accepted government auditing standards (GAGAS) as defined by the General Accounting Office's (GAO) Governmental Auditing Standards (GAO Yellow Book).

2. Deliverables

a. Audit Plan

The auditor will develop a performance audit plan based on a comprehensive risk assessment model, developed by the auditor, which identifies in priority order the functions or operational areas to audit (i.e., CIRM functions and operational areas, in order of priority, that could be examined within the available audit budget in addition to the statutorily-defined examination of contracts, grants and loans, and intellectual property). The detailed audit plan will adhere to GAGAS and the GAO's Auditing Standards and provide the methodology the auditor will use to address the audit objectives. The audit plan will describe both the nature and extent of audit procedures to be used for gathering and analyzing evidence, including the specific steps and tests the auditors will perform. The auditor will design the audit methodology to obtain sufficient, appropriate evidence to address the audit objectives, reduce audit risk to an acceptable level, and provide reasonable assurance that the evidence is sufficient and appropriate to support the findings and conclusions. The plan will include the expected dates for completing field work for each audit objective.

b. Draft Report

The auditor will provide a written draft performance audit report that contains observations, conclusions, and actionable recommendations for CIRM. The draft audit report must be fully supported with sufficient and appropriate evidence as required by the GAO's Government Auditing Standards. The auditor must communicate its findings, conclusions, and recommendations and provide CIRM management the opportunity to review and comment, per GAGAS.

c. Draft Final Report

The auditor will provide a written draft final performance audit report that contains observations, conclusions, and actionable recommendations for CIRM. The draft final audit report must be fully supported with sufficient and appropriate evidence as required by the GAO's Government Auditing Standards and contain the following: 1) executive summary; 2) the objectives, scope, and methodology of the audit; 3) the audit results, including findings, conclusions, and recommendations, as appropriate; 4) a

statement about the auditors' compliance with generally accepted government auditing standards; 5) a summary of the views of CIRM management; and 6) if applicable, the nature of any confidential or sensitive information omitted. In addition, the auditor will create a presentation (i.e., PowerPoint) to convey the results of the audit and make the presentation to CIRM management.

d. Final Report

The auditor will submit a final audit report to CIRM management, including an executive summary and CIRM management's response to the recommendations. The auditor will provide a minimum of five hard copies and one electronic copy (on CD) of the final report. The auditor should also be prepared to make the presentation to the ICOC Governing Board or a designated subcommittee, which may meet anywhere in California

3. Performance Expectations

CIRM has the following performance expectations of the auditor in providing these services. The auditor must:

- Conduct all activities in accordance with the agreed upon contract terms and with the GAO's Governmental Auditing Standards.
- Be sensitive to the impact that requests for information or documentation have on the CIRM staff's ability to carry out their normal duties and responsibilities.
- Be on-site in CIRM's office to conduct interviews, collect evidence, conduct entrance and exit conferences, or carry out any other activities that require direct interaction with CIRM staff or direct examination of CIRM documentation. No confidential documentation will be allowed to leave CIRM's premises. The balance of the work should be conducted in the audit firm's offices.
- Notify CIRM management prior to the release of the final draft audit report to the discovery of any significant issues per GAGAS. Inform CIRM management if CIRM staff has not provided sufficient information or adequate documentation requested on a particular topic. Prior to the release of the final draft report, the auditor will provide CIRM management an opportunity to explain its perspective on the issue and/or provide the necessary documentation or information.
- Maintain the strictest confidentiality regarding any issues relating to the audit's subject matter prior to the public release of the audit final report. Those within CIRM must have a clear business need to know and those outside CIRM must be authorized by law or regulation to receive the information. The auditor may contact other jurisdictions or agencies to obtain information where the contact is reasonable or necessary to complete the audit.
- Deliver all work products in a timely manner, with a goal of having the final report completed by March 30, 2012, with subsequent presentation to the ICOC.

- Communicate issues, findings, and recommendations clearly and succinctly. CIRM values the discovery of significant issues and recommendations related to the audit objectives and scope. The quality of the issues raised and recommendations made is more important than the quantity.

4. Duration of Contract

The contract for these services will cover a seven (7) month period, starting on October 3, 2011 and ending April 30, 2012. The starting and ending dates may change if CIRM makes an award earlier than expected or if CIRM cannot execute the agreement in a timely manner due to unforeseen delays. CIRM reserves the right to extend the term of the resulting agreement as necessary to complete or continue the services.

5. Budget

Cost proposals must not exceed \$250,000.

C. Procurement Information

This section of the RFP contains the anticipated schedule for the procurement and describes the procurement events as well as the conditions governing the procurement.

1. Key Action Dates

Action	Time (if applicable)	Date
CIRM issues RFP		June 13, 2011
Bidders submit email of intent to bid	3:00 pm	July 6, 2011
Bidders submit written questions	3:00 pm	July 6, 2011
CIRM responds to written questions		July 22, 2011
Bidders submit proposals	5:00 pm	August 5, 2011
CIRM evaluates proposals*		August 8-19, 2011
CIRM selects finalists (at its sole discretion)*		August 19, 2011
CIRM conducts interviews (at its sole discretion)*	TBD	August 26, 29, 30, 2011
CIRM notifies apparent successful bidder*		September 1, 2011
Final negotiations, award contract		September 1-30, 2011
Successful bidder commences work		October 3, 2011

** These dates are subject to change at CIRM's sole discretion.*

2. Explanation of Events

a. Issue RFP

This RFP has been issued by the California Institute for Regenerative Medicine. Copies of this RFP, including supporting documents, may be obtained from CIRM's website at http://www.cirm.ca.gov/jobs_RFPs.

b. Submit Intent to Bid

All prospective bidders are encouraged to register their Intent to Bid as soon as possible after release of the RFP to provide greater assurance that they will receive written responses to questions or other notifications about this RFP. Requesting the RFP does not constitute submission of intent to bid. However, there is no penalty for not submitting an Intent to Bid. Any prospective bidder may pose written questions or submit a proposal even if they have not submitted an Intent to Bid.

To submit an Intent to Bid, prospective bidders should email their firm's name, person to contact, email address, mailing address, physical address, daytime telephone number, and fax number to Cynthia Schaffer at PerformanceAuditRFP@cirm.ca.gov. In the subject line of the email, state the following: *Intent to Bid on RFP #2272: Your Firm's Name*.

c. Submit Written Questions

Potential bidders may submit written questions via email or fax until 3:00p.m. PDT on July 6, 2011 as indicated in Section C.1, Key Action Dates. The Contract Administrator will not respond to questions submitted in any other manner or format. Questions should be emailed to PerformanceAuditRFP@cirm.ca.gov or faxed to (415) 396-9141, to the attention of Cynthia Schaffer. In the subject line of the email or fax cover sheet, state the following: *Questions for RFP #2272: Your Firm's Name*.

When submitting a written question, bidders should provide the following information:

- Bidder's name, name of firm submitting the inquiry, mailing address, email address, area code and telephone number, and fax number;
- A description of the subject or issue in question or discrepancy found;
- RFP section, page number or other information useful in identifying the specific problem or issue in question; and
- Clarification sought, if any.

Bidders submitting inquiries by email or fax are responsible for confirming the receipt of all materials by the question deadline. Call Cynthia Schaffer at (415) 396-9241 to confirm email and/or fax transmissions.

Additional written requests for clarification of distributed answers and/or addendums must be received by the Contract Administrator no later than three (3) days after the answers and/or addendums are posted at http://www.cirm.ca.gov/Jobs_RFPs.

d. Response to Written Questions

The Contract Administrator will email written responses to all prospective bidders that submitted an Intent to Bid. In addition, the Contract Administrator will post written responses to written questions and any RFP amendments on the CIRM website at http://www.cirm.ca.gov/Jobs_RFPs. The CIRM reserves the right to post addenda until the RFP closing date and time.

e. Submission of Proposals

Proposals must be submitted in conformance with Section E, Proposal Requirements. No oral, telephone or facsimile proposals will be accepted. CIRM personnel will not merge, collate, or assemble proposal materials.

A bidder may submit an amended proposal before the deadline for receipt of proposals. Such amended proposals must be complete replacements for a previously submitted proposal and must be clearly identified as such in the transmittal letter.

Proposals must be received no later than the deadline specified in Section C.1, Key Action Dates, to the attention of the Contracts Administrator at the location listed below:

Cynthia Schaffer
Contracts Administrator
California Institute for Regenerative Medicine
210 King Street, 3rd Floor
San Francisco, CA 94107

f. Interviews of Finalists

At its sole discretion, the CIRM may require the highest ranked firms to make an oral presentation to the RFP Evaluation Committee. In the event finalists are interviewed, the oral presentations will be scheduled at the CIRM's office, located at 210 King Street, 3rd Floor, San Francisco, California. The selected finalists will have an opportunity to summarize the information provided in their written proposals, expand on their capabilities, experience, proposed approach, and work plan and answer questions from the RFP Evaluation Committee. It is important that the primary individuals assigned to the performance audit participate in the presentation and interview.

g. Final Negotiations and Contract Award

The finalist that provides the best value to the CIRM will be deemed the apparent successful bidder, subject to approval by the CIRM President. CIRM may discuss with the apparent successful bidder any deficiencies or other aspects of its proposal such as price, technical approach, and terms that could, in the opinion of CIRM, be altered or explained to enhance materially the apparent successful bidder's proposal. The scope and extent of discussions are a matter solely within CIRM's judgment. If CIRM and the apparent successful bidder cannot come to agreement on these alterations, CIRM, at its sole discretion, may elect to hold discussions with the next ranked bidder.

Upon contract award, the performance auditor shall begin service immediately.

3. Conditions of the Procurement

a. CIRM Rights

The CIRM reserves the right to do the following at any time:

- 1) Reject any or all proposal(s), without indicating any reason for the rejection;
- 2) Waive or correct any minor or inadvertent defect, irregularity or technical error in a proposal or the RFP process, or as part of any subsequent contract negotiation;
- 3) Request that bidders supplement or modify all or certain aspects of their proposals or other documents or materials submitted;
- 4) Terminate the RFP and, at its option, issue a new RFP, or decline to reissue the RFP;
- 5) Extend a deadline specified in this RFP, including deadlines for accepting proposals;
- 6) Negotiate with any or none of the bidders;
- 7) Modify in the final agreement any terms and/or conditions described in this RFP;
- 8) Terminate failed negotiations with a bidder without liability, and negotiate with other bidders;
- 9) Disqualify any bidder on the basis of a real or apparent conflict of interest, or evidence of collusion that is disclosed by the proposal or other data available to CIRM;
- 10) Eliminate, reject or disqualify a proposal of any bidder who is not a responsible bidder or fails to submit a responsive offer as determined solely by CIRM;
- 11) Accept all or a portion of a bidder's proposal; and

- 12) Undertake any investigation, including, without limitation, contacting third parties, for assessing the background, experience, qualification and expertise of any or all bidders.

b. Bidders' Costs

Bidders are responsible for all costs of developing and submitting a proposal package, interviews, or any other bidder's costs associated with this solicitation. Such costs cannot be charged to CIRM or included in any cost element of a bidder's price offering.

c. Contract Terms and Conditions

The bidder that is awarded a contract as a result of this procurement must comply with the terms, including insurance requirements, in CIRM's standard Independent Consultant Agreement (see Appendix 1). All prospective bidders must indicate in the Proposal Transmittal Letter that they understand and will comply with the terms and conditions in the Independent Consultant Agreement.

d. Follow-on Work

The bidder that is awarded a contract as a result of this procurement is precluded from bidding on any subsequent contract or performing any follow-on work related to the findings and conclusions presented in the final performance audit report.

e. California Public Records Act

Under the California Public Records Act, the records of State agencies are generally available to the public upon request. A proposal that a bidder submits will be a public document. If a bidder is awarded a contract as a result of this procurement, the contract will be a public document.

The Public Records Act allows CIRM to withhold documents, or parts of documents, that reveal trade secrets or information that is confidential or proprietary, or information that would invade personal privacy. Bidders should submit their proposals in a form that does not include such information. If a bidder wishes to include non-public information, the bidder should place that information in a separate envelope labeled "Confidential," and include a brief explanation of the reason the information is non-public. If a bidder does not provide an adequate basis for withholding the information, CIRM is required to make it available to the public. CIRM reserves the right to make the final determination whether to withhold or produce a document or portion of a document in response to a Public Records Act request. If CIRM withholds information at the bidder's request, the bidder may be required to litigate any claim of trade secret asserted.

CIRM is not permitted to provide legal advice about the Public Records Act and/or its exemptions. The following documents provide additional information about CIRM's obligations under the Public Records Act:

- CIRM Public Records Access Guide
<http://www.cirm.ca.gov/faq/pdf/guidelines.pdf>
- Summary of the California Public Records Act
http://www.ag.ca.gov/publications/summary_public_records_act.pdf

D. Bidder Qualifications

CIRM expects the auditor to demonstrate a high degree of experience, training and proficiency in the conduct of performance audits. The bidder should have extensive background in both performance auditing of governmental agencies and grants programs. Performance audit experience in the federal government, in California and other states, or in non-profit funding organizations may be considered as satisfying this requirement. In addition, CIRM expects that the auditor will comply with GAGAS as defined in the GAO's Yellow Book and will maintain appropriate expertise at the firm's own expense. The bidder must meet, at a minimum, the following requirements:

- Firm must have an office established in the State of California.
- Firm must be licensed to do business in the State of California.
- Firm must have conducted within the last five (5) years, at least three (3) performance audits or management reviews of governmental agencies, preferably agencies engaged in grants administration. Performance audit experience in the federal government, in California, and other states may be considered as satisfying this requirement. Performance audit experience with non-profit grant funding organizations would also be considered valuable.
- Firm must provide copies (hard-copy or electronic) of at least two (2) performance audit reports that the firm has performed within the past five (5) years in accordance with GAO Government Auditing Standards. The firm must have had primary responsibility for performing the majority of the work on each audit.
- Firm must agree to retain working papers and other performance audit work products for seven (7) years. In retaining these records, the firm should give appropriate consideration to the sensitivity of the information contained in the documents to prevent the unauthorized release of confidential information.
- Firm must have sufficient staff to provide to CIRM the performance auditing services and deliverables described in Section B, Statement of Work.
- Firm must demonstrate that in all matters relating to the performance audit work, the audit organization and the individual auditor are free both in fact and

appearance from personal, external and organizational impairments to independence.

- Firm must not be a publicly traded corporation, or subsidiary thereof, that is incorporated offshore, but for the public trading of the corporation's stock the principal market is the United States.
- Firm must be able to comply with the terms, including all of the insurance requirements, in CIRM's standard Independent Consultant Agreement (see Appendix 1) and acknowledge compliance with these terms in the Proposal Transmittal Letter.

E. Proposal Format and Organization

1. Number of Copies

Bidders must provide one (1) original, one (1) electronic, and four (4) identical copies of their proposal to the location specified in Section C.2.e on or before the closing date and time for receipt of proposals. The original must be stamped "Original" and contain original signatures on the necessary forms. The remaining sets must be identical copies of the original.

2. Proposal Format

All proposals should be typewritten on standard 8 ½ x 11 paper (larger size paper is permissible for charts, spreadsheets, etc.) and placed within a binder with tabs delineating each section. Bidders should utilize both sides of the paper where practical.

a. Letter of Transmittal

The bidder must provide a Letter of Transmittal that contains the following elements:

1. A summary of the firm's pertinent expertise, skills, client base and services provided.
2. A primary contact for the proposal, including the name, address, telephone numbers and email address.
3. Statement that if awarded the contract as the primary contractor, the bidder will accept full responsibility for successful performance of the entire scope of work.
4. Statement that the firm acknowledges and will comply with the terms, including all of the insurance requirements, in CIRM's standard Independent Consultant Agreement (see Appendix 1).

b. Experience and Qualifications of the Firm

This section of the proposal should demonstrate the bidder's qualifications, experience and capacity to conduct this performance audit. Bidders must provide references and work samples to substantiate this experience. This section of the bidders' proposals should include the following elements:

- 1) Provide Firm Information utilizing Attachment 1.
- 2) Provide the following information:
 - Legal status of the firm (sole proprietorship, partnership, corporation, etc.) and the year the entity was organized to do business as the entity now exists.
 - If the firm, any principals of the firm, or any proposed subcontractor contracted with CIRM during the past 48 months, describe the work and/or provide other information available to identify the contract.
 - If any employee of the firm or employee of proposed subcontractors was an employee of CIRM during the past 24 months or is now an employee of CIRM, identify the individual by name, job title or position held, hire date, and separation date (if applicable).
 - If the bidder, including any proposed subcontractors, has had a public sector contract terminated for default in the past three (3) years, describe such incident. Termination for default is defined as notice to stop performance due to the firm's nonperformance or poor performance. Bidders will submit full details of the terms for default, identify the other party (including the name, address, and phone number), and present the bidder's position on the matter. CIRM will evaluate the facts and may, at its sole discretion, reject the proposal on the grounds of the past experience. If the bidder has experienced no such termination for default in the past three (3) years, so indicate.
- 3) Describe the bidder's organization, including main business location, office location from which bidders' staff will work on this performance audit, names of principals, number of employees, client base, areas of specialization and expertise, and any other information that will assist the RFP Evaluation Committee in formulating an opinion about the stability and strength of the firm and corporate status.
- 4) Describe how the bidder meets the minimum qualifications specified in Section B, Bidder Qualifications.
- 5) Describe recent and relevant experience (past five (5) years) that the bidder and all subcontractors have in conducting performance audits or management reviews of government organizations, programs or activities, or other audit experience that will assist in the performance of this audit.
- 6) Utilizing the References Form (Attachment 2), provide a minimum of three (3) references that can be checked by the RFP Evaluation Committee.

- 7) Provide one (1) copy each (hard-copy or electronic) of at least two (2) performance audit reports and that the firm has performed within the past five (5) years in accordance with GAO Government Auditing Standards. The firm must have had primary responsibility for performing the majority of the work on each audit.

c. Experience and Qualifications of Proposed Personnel

It is essential that assigned team members are committed for the duration of the audit and that reporting lines are clear. This section of bidders' proposals should include the following elements:

1. Provide an organizational chart indicating lines of authority for all key personnel, including subcontractors, who will be involved in the performance audit. On the organizational chart, bidders should clearly identify the lead individual assigned to work directly with CIRM management who has the authority to resolve any problems, issues, or concerns.
2. Provide a description of the proposed audit team structure and internal quality control system to be used during the course of the project, including any subcontractors. The bidder should indicate who within the firm's organization will have prime responsibility and final authority for all work products. The bidder must demonstrate its team structure meets the requirements of GAO Yellow Book general standards 3.40 through 3.49 for "Competence," and its internal quality control system meets the requirements of general standards 3.5 through 3.64, pertaining to "Quality Control and Assurances."
3. Provide appropriate leadership, management skills, authority, and resources to guide this project. The assignment of a skilled project manager will play a large role in fulfilling the requirement. The bidder must provide a résumé for the project manager and include information on the individual's specific skills related to this project, education, experience, significant accomplishments and responsibilities assumed on other similar projects.
4. Identify responsibilities and roles of the key staff, including any subcontractors, who will be assigned to the project. Include any anticipated involvement of CIRM staff and describe their level of participation.
5. Demonstrate that all staff proposed meet the following:
 - Possess the knowledge of GAGAS applicable to this audit and the education, skills and experience to apply such knowledge to the audit being performed;
 - Possess general knowledge of the type of environment in which CIRM operates and the subject matter under review;

- Possess the skills to communicate clearly and effectively both orally and in writing; and
 - Are free both in fact and appearance from personal, external and organizational impairments to independence in all matters relating to this performance audit.
6. Provide résumés for the named key staff, which must include information on the individual's specific skills related to this project, education, experience, significant accomplishments, and responsibilities assumed on other projects, and any other pertinent information. Résumés for subcontractor personnel will clearly display the word "SUBCONTRACTOR" on the top of the first page.

d. Statement of Work Approach

The bidder's proposal must include a description of the bidder's overall approach and a high-level workplan for providing the services and deliverables indicated in Section B, Statement of Work.

Bidders are requested to not simply repeat the "Yellow Book" in their proposal. Please elaborate upon how your firm would apply the GAGAS and "Yellow Book" framework to produce the most relevant, actionable, and value-added performance audit report for CIRM.

e. Financial Capacity

Bidders must submit copies of the most recent year's independently audited financial statements, as well as those for the preceding two (2) years, if they exist. The submission must include the audit opinion, balance sheet, income statement, retained earnings, cash flows, and notes to the financial statements. If independently audited financial statements do not exist, the bidder must state the reason and, instead, submit sufficient information such as the latest Dun and Bradstreet report to enable the RFP Evaluation Committee to determine the financial stability of the bidder. CIRM may request and the bidder must supply any additional financial information requested in a timely manner.

f. Cost Proposals

Proposers must fully complete Cost Detail Table (Attachment 3) that summarizes: 1) proposed cost per project staff member, and 2) proposed cost per deliverable. The total project cost cannot exceed \$250,000. Note that the hourly rates must be fully loaded to include all professional fees, support services, travel, and any other expenses.

g. Required Attachments

- Firm Information (Attachment 1)
- References Form (Attachment 2)
- Cost Detail (Attachment 3)

h. Other Contents of Proposal

Bidders may include any relevant information and pertinent exhibits in the proposal. Proposals are to be prepared in such a way as to provide a straightforward, concise delineation of capabilities to satisfy the requirements of this RFP. Emphasis should be on conformance to the instructions and responsiveness to the requirements described herein, and on completeness and clarity of content.

F. Proposal Evaluation

Proposals must be complete in all respects and submitted by the dates and times shown in Section C.1, Key Action Dates. A proposal may, at the sole discretion of CIRM, be rejected if it is conditional, incomplete, or it contains any alterations of form or other irregularities.

The selection of a firm to perform the requested services will be made by a CIRM-appointed RFP Evaluation Committee that will evaluate proposals in accordance with the evaluation criteria specified in Table 4 and establish a ranking. A serious deficiency in any one criterion may be grounds for rejection. CIRM shall have the right to obtain, from any and all sources, information concerning a bidder, which is deemed pertinent to this RFP, and to consider such information in the evaluation of the bidder's proposal.

The listing of cost as an evaluation factor does not require CIRM to select the firm that submits the lowest price. CIRM intends to select the proposal which provides the best value. A proposal meeting the requirements of the RFP with the lowest price may not be selected if award to a higher priced proposal, in the judgment of the RFP Evaluation Committee, maximizes greater overall benefits to CIRM. CIRM may elect to pay a higher price to select a proposal that overall is exceptional and reasonably priced. The RFP Evaluation Committee will assess each component in the bidder's cost detail in relation to the services the bidder offers. A bidder that exceeds the requirements by providing more services, higher quality services, or more experienced staff for a reasonable price will receive the highest consideration.

Proposals will be evaluated and scored according to the criteria indicated in Table 4. The selection will be made by the RFP Evaluation Committee on the basis of the following weighted factors. The maximum points available for each criterion are noted.

Table 4: Evaluation Criteria

Criteria	Maximum Points
Clarity and Succinctness of Proposal	15
Experience and Qualifications of the Firm	45
Experience and Qualifications of Proposed Staff	45
Approach and Methodology	45
Work Samples	45
Financial Capacity	15
Cost	30
Maximum Total Possible Points:	240

CIRM reserves the right to select the top ranked firm based solely on the scoring of the written proposals and to enter directly into negotiations with said firm. However, at its sole discretion, CIRM may contact the references of the highest ranked firms and require the highest ranked firms to make an oral presentation to the RFP Evaluation Committee. In this event oral presentations will be scheduled at CIRM's office, located at 210 King Street, 3rd Floor, San Francisco, California. Selected finalists will have an opportunity to summarize the information provided in their written proposals, expand on their capabilities, experience, proposed approach and work plan and answer questions from the RFP Evaluation Committee. It is important that the primary individuals servicing the contract are present for this presentation.

Upon completion of the oral presentations, the RFP Evaluation Committee will review the material presented and determine a ranking order for the firms interviewed. Negotiations will be conducted with the highest ranked firm until a contract is awarded. If an agreement cannot be reached on contract terms, negotiations will be terminated and the next highest ranked firm will be contacted for negotiations.

List of Attachments

Attachment 1: Firm Information

Attachment 2: References Form

Attachment 3: Cost Detail

Attachment 1: Firm InformationName of firm or individual
proposed consultantBusiness or trade name, if
different from aboveBusiness Form
(check only one)

- ☐ Corporation
☐ Partnership
☐ LLC
☐ Individual/Sole Proprietor
☐ Other: _____

Mailing Address

City

State

Zip

Website

Firm Contact
Name

Email

Telephone

Fax

Total dollar amount of consultant work that the firm has
performed for CIRM in the last 12 months.

The name and position of any CIRM employee who holds a position of director,
officer, partner, trustee, manager or employee in the consultant organization, as well
as the names of any near relatives who are employed by CIRM.

Certification

I hereby certify under penalty of perjury that I am authorized by the proposed
consultant to submit this proposal on its behalf. I have reviewed all
information provided in the accompanying proposal, and it is true and
complete to the best of my knowledge.

Signature

Date

Name

Title

Attachment 2: References Form

Proposers must provide the following client information for at least three (3) prior performance audits of similar size and scope. Provide the name, title, telephone number, and email of contact persons that CIRM may contact to inquire about your firm's performance. The references should be individuals who: 1) were project leaders; 2) can validate your firm's role and responsibilities; and 3) can comment on the quality of your firm's performance.

REFERENCE CLIENT #1

Client Name	
Client Address	
Contact Name	
Contact Title	
Contact Phone #	
Contact Email	
Project Name	
Project Begin/End Dates	
Project Description	
Project Budget	

REFERENCE CLIENT #2

Client Name	
Client Address	
Contact Name	
Contact Title	
Contact Phone #	
Contact Email	
Project Name	
Project Begin/End Dates	
Project Description	
Project Budget	

REFERENCE CLIENT #3

Client Name	
Client Address	
Contact Name	
Contact Title	
Contact Phone #	
Contact Email	
Project Name	
Project Begin/End Dates	
Project Description	
Project Budget	

Attachment 3: Cost Detail

Proposers must fully complete the following cost tables that summarize: 1) proposed cost per project staff member, and 2) proposed cost per deliverable. The total project cost cannot exceed \$250,000. Note that the hourly rates must be fully loaded to include all professional fees, support services, travel, and any other expenses.

Table 3a – Cost per Staff Member

Staff Name	Project Role	(a) Rate per Hour	(b) Total Hours	(a) x (b) Staff Total Cost
Total Cost:				

Table 3b – Cost per Deliverable

<i>Deliverable 1 – Audit Plan</i>				
Staff Name	Project Role	(a) Rate per Hour	(b) Total Hours	(a) x (b) Staff Total Cost
Total Cost for Deliverable 1:				
<i>Deliverable 2 – Draft Report</i>				
Staff Name	Project Role	(a) Rate per Hour	(b) Total Hours	(a) x (b) Staff Total Cost
Total Cost for Deliverable 2:				
<i>Deliverable 3 – Draft Final Report</i>				
Staff Name	Project Role	(a) Rate per Hour	(b) Total Hours	(a) x (b) Staff Total Cost
Total Cost for Deliverable3:				
<i>Deliverable 4 – Final Report</i>				
Staff Name	Project Role	(a) Rate per Hour	(b) Total Hours	(a) x (b) Staff Total Cost
Total Cost for Deliverable 4:				

List of Appendices

Appendix 1: Independent Consultant Agreement

Appendix 2: Links to CIRM Policies and Regulations

III. COMPENSATION AND REIMBURSEMENT FOR EXPENSES

A. CIRM shall pay the Consultant for services performed on the following basis:

1. Professional Fees:

2. Other Expenses

MAXIMUM TO BE PAID UNDER THIS AGREEMENT

\$ _____

* Reimbursement for travel and per diem shall be in accordance with established CIRM rates and policies.

B. Payments shall be made upon the Consultant's submission of invoices indicating the Agreement Number and setting forth charges in accordance with rates detailed in Article III-A. Consultant must submit a completed Payee Data Record (State Standard Form 204) before CIRM will issue payment. Each invoice shall include the Consultant's taxpayer identification number (Social Security or employer identification number). Invoices shall be submitted not more frequently than monthly in arrears to:

California Institute for Regenerative Medicine
Finance Officer
210 King Street
San Francisco, CA 94107

Payment will be made in accordance with, and within the time specified in, Government Code Chapter 4.5, commencing with Section 927.

IV. REPORTING

In performing consulting services under this Agreement, the Consultant shall be accountable to CIRM and shall provide progress reports to CIRM upon CIRM's request.

V. NOTIFICATION

Notices concerning this Agreement shall be addressed as follows:

CIRM:

TO CONSULTANT:

California Institute for Regenerative Medicine
General Counsel
210 King Street
San Francisco, CA 94107

VI. TAXES

The compensation stated in Article III includes all applicable taxes and will not be changed hereafter as the result of Consultant's failure to include any applicable tax or as the result of any change in the Consultant's tax liabilities. The Consultant acknowledges that compensation payable hereunder may be subject to withholding of state and federal income tax, including state income tax subject to withholding pursuant to California Revenue and Taxation Code Sections 18661-18677.

VII. INDEPENDENT CONTRACTOR STATUS

- A. Both parties agree that in the performance of this Agreement the Consultant shall not be an agent or employee of CIRM, shall not be covered by the State's Worker's Compensation Insurance or Unemployment Insurance, shall not be eligible to participate in State employee retirement programs, and shall not be entitled to any other CIRM employee benefits.
- B. The Consultant shall be solely responsible for the conduct and control of the work to be performed by the Consultant under this Agreement, except that the Consultant is accountable to CIRM for the results of such work. The Consultant's services for CIRM shall be performed in accordance with currently approved methods and ethical standards applicable to the Consultant's professional capacity.
- C. California State Contract Code 10515 (a) states: No person, firm, or subsidiary thereof who has been awarded a consulting services contract may submit a bid for, nor be awarded a contract on or after July 1, 2003, for the provision of services, procurement of goods or supplies, or any other related action that is required, suggested, or otherwise deemed appropriate in the end product of the consulting services contract.

VIII. ASSIGNMENT OR SUBCONTRACTING

The Consultant may not assign or transfer this Agreement, or any interest or claim, or subcontract any portion of the work, without the prior written approval of CIRM. The withholding or granting of such approval is totally discretionary with CIRM. If CIRM consents to such assignment or transfer, the terms and conditions of this Agreement shall be binding upon any assignee or transferee.

IX. PROPERTY RIGHTS, INCLUDING PATENTS AND COPYRIGHTS

All written and other tangible material ("Material") produced pursuant to this Agreement by the Consultant shall be considered a work-made-for-hire under the Copyright Act. To the extent said Material does not qualify as a work-made-for-hire, Consultant hereby assigns all right, title, and interest, including, but not limited to, copyright and all copyright rights in the Material to CIRM and shall execute any and all documents necessary to effectuate such assignment. In the event Consultant uses any individual who is not a full-time employee of Consultant or uses any other entity to perform any of the work required by Consultant hereunder, Consultant shall require said individual or entity to sign an agreement before commencing work that contains identical wording to the foregoing two sentences except that the word "Consultant" shall be replaced with the individual's or entity's name.

X. CONSULTANT'S LIABILITY AND INSURANCE REQUIREMENTS

- A. The Consultant agrees to defend and, at CIRM's election, indemnify and hold harmless CIRM, its officers, agents, and employees from and against any and all claims, losses, expenses (including costs and reasonable attorney's fees), claims for injury, or damages that are caused by or result from the negligent or intentional acts or omissions or breach of this Agreement by the Consultant or its officers, employees, or agents. In addition, Consultant agrees to defend and, at CIRM's election, indemnify, and hold harmless CIRM, its officers, agents, and employees from and against any and all claims, losses, expenses (including costs and reasonable attorney's fees), claims for injury, or damages accruing or resulting to any and all contractors, subcontractors, suppliers, or any other person, firm or corporation furnishing services or supplying goods in connection with Consultant's performance of this Agreement.
- B. The Consultant shall furnish a Certificate of Insurance or statement of self-insurance (contractual liability included) showing minimum coverage as follows:

1. General Liability: Comprehensive or Commercial Form (Minimum Limits)

(i) General Aggregate (BI, PD)*	\$2,000,000
(ii) Products, Completed Operations Aggregate	\$2,000,000
(iii) Personal and Advertising Injury	\$1,000,000
(iv) Each Occurrence	\$1,000,000

* (not applicable to comprehensive form)

However, if such insurance is written on a claims-made form following termination of this Agreement, coverage shall survive for a period no less than three years. Coverage must include a Primary and Non-Contributory provision and a Severability of Interest provision. Coverage shall also provide for a retroactive date of placement coinciding with the effective date of this Agreement.

2. Business Auto Liability: (Minimum Limits) for Owned, Scheduled, Non-Owned, or Hired Automobiles with a combined single limit of no less than \$1,000,000 per occurrence. [Alternative: Business Auto Liability is waived because Consultant will not drive in the course of performing services for CIRM.]

3. Workers' Compensation: as required under California State Law.

4. Professional Liability Insurance: (Minimum Limits)

(1) Each occurrence	\$2,000,000
(2) Project Aggregate	\$2,000,000

If this insurance is written on a claims-made form, it shall continue for three years following termination of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this Agreement. The insurance must include Contractual Liability Coverage and Defense and Indemnification of CIRM by the contracting party.

5. Other insurance in amounts as from time to time may reasonably be required by the mutual consent of CIRM and the Consultant against such other insurable hazards relating to performance.

6. Certificate(s) of Insurance shall name CIRM as an additional insured under 1, 2 and 4 above, obligate the insurer to notify CIRM at least thirty (30) days prior to cancellation of or changes in any of the required insurance and include a provision that the coverage will be primary and will not participate with nor be excess to any valid and collectible insurance program of self-insurance carried or maintained by CIRM. Premiums on all insurance policies shall be paid directly by the Consultant.

XI. RECORDS ABOUT INDIVIDUALS

- A. The Consultant acknowledges that the creation and maintenance of records pertaining to individuals is subject to certain requirements set forth by the California Information Practices Act (Civil Code 1798, et seq.) and by CIRM policy. Such requirements include provisions governing the collection, maintenance, accuracy, dissemination, and disclosure of information about individuals, including the right of access by the subject individuals.
- B. If the Consultant creates confidential or personal records about an individual, as defined by the Information Practices Act, including notes or tape recordings, the information shall be

collected to the greatest extent practicable directly from the individual who is the subject of the information. When collecting the information, the Consultant shall inform the individual that the record is being made and of the purpose of the record.

- C. Records containing confidential or personal information about individuals are the property of CIRM and subject to CIRM's policies and applicable federal and state laws. The Consultant agrees to deliver all such records, including originals and all copies and summaries, to CIRM upon termination of this Agreement.
- D. The Consultant shall not use recording devices in discussions with CIRM's employees without notifying all parties to the discussion that the discussion is being recorded.

XII. EXAMINATION OF RECORDS

The Consultant agrees that CIRM and its authorized agents shall have the right to review and copy any records and supporting documentation pertaining to the performance of this Agreement including, but not limited to, all documents, records and work papers whether obtained or copied from CIRM or developed by the Consultant. Consultant agrees to maintain such records for a minimum of five (5) years after final payment, unless a longer period of records retention is stipulated. Consultant agrees to allow CIRM and its authorized agent's access to such records during normal business hours. Further, Consultant agrees to include a similar right of access in any subcontract related to the performance of this Agreement.

In accordance with state law, the Consultant agrees that CIRM, its authorized agents, the State Controller's Office, and the Bureau of State Audits (collectively, the "Auditors") shall have the right, in connection with an audit, to review and copy any records and supporting documentation pertaining to the performance of this Agreement including, but not limited to, all documents, records and work papers whether obtained or copied from CIRM or developed by the Consultant. Consultant agrees to maintain such records for possible audit for a minimum of five (5) years after final payment, unless a longer period of records retention is stipulated. Consultant agrees to allow the Auditors access to such records during normal business hours and to allow interviews of any employees who might reasonably have information related to such records. Further, Consultant agrees to include a similar right of the Auditors to audit records and interview staff in any subcontract related to the performance of this Agreement.

XIII. CONFLICT OF INTEREST

- A. The Consultant will not hire any officer or employee of CIRM to perform any service covered by this Agreement. If the work is to be performed in connection with a federal or state contract or grant, the Consultant will not hire any employee of the government agency concerned to perform any service covered by this Agreement.
- B. The Consultant affirms that to the best of his/her knowledge there exists no actual or potential conflict between the Consultant's family, business or financial interest and the services provided under this Agreement, and in the event of change in either private interests or service under this Agreement, any question regarding possible conflict of interest which may arise as a result of such change will be raised with CIRM.
- C. The Consultant shall not be in a reporting relationship to a CIRM employee who is a near relative, nor shall the near relative be in a decision-making position with respect to the Consultant.
- D. The Consultant may be required to execute a Form 700 Statement of Economic Interests as published by the Fair Political Practices Commission. Statements of Economic Interests are public documents. More information about Form 700 is available at www.fppc.ca.gov.

XIV. AFFIRMATIVE ACTION

The Consultant recognizes that as a state government contractor or subcontractor, the Consultant is obligated to comply with all state laws and regulations regarding equal opportunity and affirmative action in government contracts. When applicable, the Consultant agrees that all such laws and their implementing regulations are incorporated herein as though set forth in full. These laws include the nondiscrimination requirements of Government Code sections 12990 and 11135, and the nondiscrimination program and clause required by Title 2, Division 4, Chapter 5 of the California Code of Regulations.

XV. CONFIDENTIALITY

The Consultant shall keep confidential any information provided by CIRM or any information conveyed orally to the Consultant by CIRM with oral notification of its confidentiality (the "Confidential Information"), Consultant agrees to maintain the secrecy of CIRM's Confidential Information and agrees not to use it except in performing the Services under this Agreement and not to disclose it to anyone outside CIRM or anyone within CIRM's organization who does not have a need to know it to perform under this Agreement. This non-disclosure provision shall not apply to any of the following:

1. Information which the Consultant can demonstrate by written records was known to him or her prior to the effective date of this Agreement;
2. Is currently in, or in the future enters, the public domain other than through a breach of this Agreement or through other acts or omissions of the Consultant; or
3. Is obtained lawfully from a third party.

XVI. APPLICABLE LAW

The laws of the State of California shall govern this Agreement.

XVII. TERMS TO BE EXCLUSIVE

This Agreement constitutes the entire understanding between the parties regarding the subject matter hereof and supersedes any prior understanding between the parties, oral or written, regarding the same subject matter.

XVIII. WAIVER OR MODIFICATION OF TERMS

No waiver, amendment or other modifications of the terms of this Agreement shall be binding upon either party unless expressed in writing and signed by both parties hereto.

XIX. STANDARD FOR PERFORMANCE

The parties acknowledge that CIRM, in selecting the Consultant to perform the services hereunder, is relying upon the Consultant's reputation for excellence in the performance of the services required hereunder. The Consultant shall perform the services in the manner of one who is a recognized specialist in the types of services to be performed. All deadlines set forth in the Agreement are binding and may be modified only by subsequent written agreement of the parties. The Consultant shall devote such time to performance of its, her, or his duties under this Agreement as is reasonably necessary for the satisfactory performance of such duties within the deadlines set forth herein. Nothing in the foregoing shall be construed to alter the requirement that time is of the essence in this Agreement.

XX. EXCLUSION.

Independent Consultant warrants that it is not excluded from participation in any governmental sponsored program, including, without limitation, the Medicare, Medicaid, or Champus programs (<http://exclusions.oig.hhs.gov/search.aspx>) and the Federal Procurement and Nonprocurement Programs

(<http://www.epls.gov/eplsearch.do>). This Agreement shall be subject to immediate termination in the event that the Independent Consultant is excluded from participation in any federal healthcare or procurement program.

XXI RESOLUTION OF DISPUTES

If the Consultant disputes any action by CIRM arising under or out of the performance of this contract, the Consultant shall notify CIRM of the dispute in writing and request a claims decision. CIRM shall issue a decision within 30 days of the Consultant's notice. If the Consultant disagrees with CIRM's claims decision, the Consultant shall submit a formal claim to the President of CIRM. The decision by the President of CIRM shall be final and conclusive on the claim unless the decision is arbitrary, capricious or grossly erroneous or if any determination of fact is unsupported by substantial evidence. The decision may encompass facts, interpretation of the contract and determinations or applications of law. The decision shall be in writing following an opportunity for the Consultant to present oral or documentary evidence and arguments in support of the claim. Consultant shall continue with the responsibilities under this Agreement during any dispute.

XXII SURVIVAL.

The following sections survive the expiration or early termination of this Agreement: IX, X, XI, XII, XV, XVI, XXI and XXII.

INDEPENDENT CONSULTANT

THE CALIFORNIA INSTITUTE FOR
REGENERATIVE MEDICINE

Signature Date

Date

Name _____

Title _____

Company _____

Item 6445-502-6047001/H&S Code 125291.20/Statutes 2004/ FY 10/11
Account/Fund to be charged

Appendix 2: Links to CIRM Policies and Regulations

Contracts Policy

http://www.cirm.ca.gov/files/PDFs/Administrative/Contracting_Policy_Adopted_20100819.pdf

Grants Administration Policy

CIRM Grants Administration Policy for Academic and Non-Profit Institutions:

http://www.cirm.ca.gov/files/Regulations/NPGAP_042809a.pdf

CIRM Grants Administration Policy for For-Profit Organizations:

http://www.cirm.ca.gov/reg/pdf/Reg100501_OAL.pdf

Loan Administration Policy

http://www.cirm.ca.gov/files/Regulations/LAP.OAL_REVIEWED.FINAL_.pdf

Intellectual Property Regulations

See sections 100600 – 100611 at: <http://www.cirm.ca.gov/cirm-operations/Regulations>